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**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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Echo Bay Pharmaceuticals, LLC,

Plaintiff,

-v-

Torrent Pharma Inc.,

Defendant.

1:20-CV-06345-BCM

**MEMORANDUM OF LAW IN  
SUPPORT OF DEFENDANT  
TORRENT PHARMA INC.'S  
MOTION TO DISMISS SECOND  
AMENDED COMPLAINT**

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## **INTRODUCTION**

Defendant Torrent Pharma Inc. (“Torrent”) respectfully submits this memorandum of law in support of its Motion to dismiss Plaintiff Echo Bay Pharmaceuticals, LLC (“Echo Bay”)’s Second Amended Complaint (ECF No. 91) (“SAC”) to address the new allegations added through Echo Bay’s recent amendment.<sup>1</sup>

This action arises out of the Co-Development Settlement Agreement (“CSA”), entered into between Echo Bay and Torrent’s predecessor, Bio-Pharm, Inc. (“BPI”), in January 2018 in anticipation of Torrent’s acquisition of BPI. The CSA governs the parties’ co-development activities that Echo Bay began with BPI in 2015, which include four generic pharmaceutical products for which the parties have filed Abbreviated New Drug Applications (“ANDAs”) for FDA approval. The ANDA process can be uncertain and lengthy—requiring years of extensive effort to demonstrate that the product meets the FDA’s requirements for approval of a generic drug. Echo Bay filed this action when it became dissatisfied with the pace of the parties’ co-development and blamed Torrent for delays in receiving FDA approval of the ANDAs. Echo Bay alleges that equipment issues at one of Torrent’s manufacturing facilities have prevented ANDA approval, and has suggested that this litigation turns on whether Torrent acted “reasonably, diligently and prudently” in its efforts to develop the products. FAC ¶ 121. However, Echo Bay does not and cannot identify any term in the CSA that plausibly assigns the risk of unsuccessful co-development solely to Torrent. On the contrary, the CSA grants Torrent, among other rights, the expressly contemplated option to stop contributing Development Expenses or otherwise cease

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<sup>1</sup> Pursuant to this Court’s Order dated August 16, 2021 (ECF No. 90), Torrent continues to rely upon its memorandum and reply in support of its prior Motion to Dismiss (ECF No. 41, 48) (“MTD”) with respect to the claims previously asserted in the First Amended Complaint (ECF No. 38) (“FAC”). Torrent, as it must, submits this motion to dismiss assuming that the allegations in the SAC are true. Torrent has not answered those allegations and strongly disagrees with the story told in Echo Bay’s pleadings.

development activities for a product at any time. ECF No. 91-1 at 11-12. As Torrent articulated in the MTD, the factual allegations in the FAC failed to establish a plausible claim that Torrent breached any provision of the CSA.

The only differences between the FAC and SAC are Echo Bay's new allegations that Torrent breached Section 8.4 of the CSA by ceasing development of Fluocinonide and not assigning the product to Echo Bay. Echo Bay omits that Section 8.4 requires Echo Bay to "choose to continue to develop" Fluocinonide and "initially incur one hundred percent (100%) of the remaining Development Expenses for" Fluocinonide. Echo Bay does not allege it chose to continue developing Fluocinonide, or that it was willing to incur 100% of the remaining Development Expenses. Echo Bay cannot plausibly allege Torrent breached Section 8.4 when Echo Bay does not allege that Section 8.4 was even triggered.

Moreover, these new allegations do not cure the deficiencies in the FAC that were the subject of the MTD, and in fact support Torrent's position that the claims asserted in the FAC should be dismissed. Echo Bay's attempt to now change the direction of the case by pursuing an entirely different and inconsistent theory of liability—after nearly a year of extensive discovery based upon its previously asserted theories of liability—does not change the fact that the claims asserted in the FAC (and maintained in the SAC) do not state a cause of action upon which relief can be granted. Echo Bay's attempts to muddle the issues in this case by asserting conflicting and inconsistent allegations, based on a "new" theory of liability it previously abandoned for strategic reasons, should be disregarded.

#### **ALLEGATIONS IN THE SECOND AMENDED COMPLAINT**

Echo Bay's allegations arise out of the parties' co-development activities, as governed by the CSA, with respect to the four "Active Products" as defined in the SAC: Fluocinolone Acetonide

Solution .01%, Fluocinonide Solution 5%, Pyridostigmine Oral Syrup, and Gabapentin Solution.<sup>2</sup>  
 See SAC ¶ 44.

Echo Bay had alleged in the FAC—and continues to allege in the SAC—that Torrent breached the CSA under two separate and distinct set of facts: (1) Torrent allegedly halted development of the Active Products when it closed the Levittown Facility for necessary renovations in 2019; and (2) Torrent allegedly failed to reimburse Echo Bay for an invoice issued by Nines Consult Pharma (which Echo Bay isn’t sure it paid). With respect to the first theory, Echo Bay alleged that Torrent’s cessation of development activities in connection with closing the Levittown Facility constituted a breach of the CSA because Torrent had an obligation “to continue Development and Commercialization of the Active Products in a reasonable and prudent matter.” SAC ¶¶ 54; 86-93. The second theory relates to an entirely separate set of facts concerning the Nines Consult Pharma invoices, and has no legal or factual connection to Echo Bay’s other allegations regarding Torrent’s efforts to develop and commercialize the Active Products. SAC ¶¶ 94-104. Torrent addressed the second theory in its previous briefs. ECF Nos. 42 at 12-13, 48 at 4-5.

In addition to these two prior theories from the FAC, the SAC now adds a third set of allegations: that Torrent allegedly breached Section 8.4 of the CSA with respect to Fluocinonide. SAC ¶¶ 74-85; 118(e); 122(h). Specifically, Echo Bay alleges that Torrent withdrew the ANDA for Fluocinonide with the FDA and thus “expressly stopped developing Fluocinonide.” SAC ¶¶ 76-78. Echo Bay alleges that § 8.4(a)(ii) provides that Torrent had a duty to assign to Echo Bay its interest in, and right to develop and commercialize, Fluocinonide within ninety (90)

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<sup>2</sup> Echo Bay’s definition of “Active Products” and factual allegations relating thereto are identical between the FAC and SAC, with the exception of the new allegations discussed below. In both complaints, Echo Bay includes Felbamate Suspension as an “Active Product,” but Exhibit B to the complaints shows that Felbamate Suspension was assigned to Echo Bay in December 2018. ECF Nos. 8-2, 91-2.

days of the alleged cessation of development of Fluocinonide, and that Torrent breached § 8.4 by failing to do so. SAC ¶¶ 82-84. Section 8.4(a) of the CSA provides, in relevant part:

Pre-ANDA Products. At any time prior to the date on which the FDA approves an abbreviated new drug application [], either Party may choose to cease contributing Development Expenses with regard to that Product by notifying the other Party in writing []. Regardless of whether or not [Torrent] provides such written notice, [Torrent] is deemed to have ceased Development of the Product . . . if no significant Development activities with regard to a Product have occurred over a given successive twelve (12) month period and such inactivity is not due to actions or omissions of a Third Party or events outside the control of [Torrent]. In such an event, the other Party [] may choose to continue to develop such Pre-ANDA Non-Development Product and initially incur one hundred percent (100%) of the remaining Development Expenses for such Product.

ECF No. 91-1 at 11-12. The subsections of § 8.4(a) then set forth the parties' rights and obligations in the event that Torrent ceases Development of a Pre-ANDA Product. *Id.* Unlike Echo Bay's prior allegations that Torrent failed to develop and commercialize each of the Active Products in a "reasonable and prudent manner," Echo Bay's new allegations regarding § 8.4(a)(ii) relate solely to the development of Fluocinonide. Echo Bay does not allege that Torrent had an obligation to assign any of the other Active Products under § 8.4, nor does it allege that Torrent expressly or impliedly ceased development of any of the other Active Products separately from the closure of the Levittown Facility.

Indeed, Echo Bay originally alleged that Torrent ceased development of the other three Active Products, but then removed these allegations after Torrent sought Judge Castel's permission to move to dismiss the original complaint. *Compare* ECF No. 1 ¶¶ 76-95 *with* ECF No. 38 ¶¶ 104-116. Echo Bay's reason for doing so is easy to understand—the presence of § 8.4, which permits either party to cease development *for any reason* and articulates the parties' obligations if a party

does so, is flatly inconsistent with Echo Bay's claim that Torrent does not have a right to cease development and must develop in a "reasonable and prudent manner[.]".

Thus, the new allegations in the SAC are legally inconsistent with Echo Bay's prior arguments. As set forth in Torrent's prior motion to dismiss, Echo Bay's claims in the FAC fail because Torrent had no obligation to continue development under the CSA. And Torrent's new claims in the SAC, which clearly admit that Torrent has the right to cease development, likewise fail because Echo Bay does not allege that it chose to continue developing Fluocinonide while bearing all of the remaining development costs.

### **ARGUMENT**

#### **I. Echo Bay's New Allegations Fail on the Merits**

Echo Bay's revived theory under § 8.4 of the CSA fails on the merits. Assuming that the breach of § 8.4 claim is plead in the alternative to Echo Bay's other breach of contract theories, the basis for this new claim is very narrow. Echo Bay alleges that Torrent's conduct constituted a cessation of the development of Fluocinonide within the meaning of § 8.4(a), and alleges that Torrent failed to perform its obligations under § 8.4(a) that are triggered by such cessation of development. SAC §§ 77-85. Specifically, Echo Bay alleges that Torrent had an obligation to assign all title and interest in Fluocinonide to Echo Bay within ninety (90) days of an express or deemed cessation of development of Fluocinonide. *Id.* § 83. For purposes of this claim, therefore, Echo Bay asks the Court to assume that there is no dispute that Torrent was within its contractual rights to cease development of Fluocinonide, thus triggering Echo Bay's alleged rights under § 8.4(a). *Id.* §§ 78-79 (noting that Torrent was deemed to have ceased development within the meaning of § 8.4).

Despite Echo Bay's conclusory allegations, its allegations regarding Torrent's conduct do not actually establish any breach of § 8.4(a). The rights and obligations under § 8.4(a) are not



unilateral. Under the plain language of § 8.4(a), once Torrent has ceased development of any product—either expressly, by notifying Echo Bay in writing, or impliedly by performing “no significant Development activities . . . over a given successive twelve (12) month period”—then § 8.4(a) is triggered such that Echo Bay “may choose to continue to develop” the ceased product and initially incur 100% of the remaining Development Expenses for such product. ECF No. 91-1 at 12. It is only after such an election takes place that the remedies provided under § 8.4(a)(ii)—upon which Echo Bay relies for its assertion that it was entitled to assignment—are triggered. Therefore, in order to be entitled to assignment of Fluocinonide under § 8.4(a), Echo Bay must have chosen to continue its development and been willing to incur the remaining Development Expenses for it.

Echo Bay does not allege that it ever elected to take over the development of Fluocinonide and assume the remaining Development Expenses for the product, either within 90 days of the alleged cessation of development or otherwise. Echo Bay thus does not allege that it satisfied the prerequisites under § 8.4(a) such that it was entitled to assignment, or any other relief, under § 8.4(a)(ii). The new allegations in the SAC cannot sustain a claim for breach of § 8.4(a).

## **II. Echo Bay’s New Section 8.4 Allegations Were Previously Abandoned for Strategic Reasons**

Prior to the SAC, Echo Bay’s main theory of liability in this case—and its primary basis for damages—had been its argument that Torrent’s failure to develop the Active Products when it closed the Levittown Facility constituted a breach of the CSA because Torrent had a duty to diligently pursue development of the Active Products. *See* ECF No. 44. Echo Bay’s new allegations that Torrent was allowed to stop development of Active Products at any time, but breached § 8.4(a) of the CSA by not assigning Fluocinonide, following the alleged cessation of

Development of the Product, are inconsistent with its prior claims under the FAC and waived by its prior abandonment of its theory that Torrent breached by ceasing development.

While a plaintiff is permitted to plead alternative and even inconsistent theories of its case, such latitude is limited where a party seeks to reverse course after previously asserting a contrary position for strategic purposes. *See Rosenshein v. Kleban*, 918 F. Supp. 98, 104 (S.D.N.Y. 1996) (“This is precisely the sort of ‘about-face’ that undermines the integrity of the [court] process”). Echo Bay should not be permitted to now proceed on its § 8.4 theory, which it previously waived for strategic reasons, after pursuing this litigation for the past year under entirely different and inconsistent theories and allegations. To date, the parties have engaged in extensive discovery, including written discovery, third-party subpoenas, and Torrent’s production of tens of thousands of documents. All of the litigation and burdensome discovery conducted over the past year has been based upon the theories of liability asserted in the FAC. Litigating the § 8.4 theory is a different dispute, presenting only two questions related to liability: (1) was § 8.4 triggered, and if so, (2) did Torrent comply with § 8.4.<sup>3</sup> This would not be the plenary inquisition into Torrent’s pharmaceutical development that Echo Bay has been waging for the last year.

Echo Bay could have maintained its allegations that implicate § 8.4 in the FAC, but specifically abandoned those claims in order to avoid dismissal nearly a year ago. These “new” allegations relating to § 8.4 should be deemed waived based on Echo Bay’s express conduct in amending the FAC to specifically abandon those claims, and then proceeding for the past year under entirely different theories of liability and damages. To permit the new claims to go forward would effectively restart the case and bring the parties back to the start of discovery, to re-litigate

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<sup>3</sup> If monetary damages are available for an § 8.4 violation (which is hardly a given), those damages are also much narrower than Echo Bay’s exorbitant lost profits theory. *See* ECF No. 48 at 2. Echo Bay’s damages would be no more than non-speculative monetary harm it sustained from any delay in compliance with § 8.4 obligations.

this action under an entirely different theory. Echo Bay's claims based on the allegations that Torrent breached § 8.4 by failing to assign Fluocinonide should be dismissed for waiver.

### **III. The New Allegations Do Not Support Echo Bay's Previously Asserted Claims**

Finally, none of the new allegations in the SAC support Echo Bay's previously asserted claims, which were the subject of the MTD briefing. In the MTD, Torrent explained that the FAC should be dismissed because neither of Echo Bay's two theories of liability support a plausible ground for recovery. *See* ECF No. 42 at 9-23. There is no dispute that the new allegations proposed by Echo Bay have no connection to the Nines Consult Pharma issue, so Torrent stands by its prior MTD briefing with respect to the deficiencies in that theory of liability and maintains that any claim(s) based on the invoices should be dismissed with prejudice. *Id.* at 12-14; ECF No. 48 at 4-5.

As to Echo Bay's "reasonable and prudent" development theory, the new allegations in the SAC not only fail to lend additional support to Echo Bay's position, but in fact contradict it. For the reasons discussed in Torrent's MTD and Reply, none of the provisions of the CSA conferred on Torrent any duty, whether express or implied, to diligently pursue development of the Active Products. *See* ECF No. 42, 48. Rather, the CSA expressly contemplates and provides Torrent with the option to unilaterally cease development, because that possibility is articulated in § 8.4. The fact that Echo Bay is now pursuing a different theory of liability based on the alleged cessation of product development and breach of § 8.4 only supports Torrent's position that no express or implied term of the CSA required Torrent to diligently pursue development of any product.

In its attempt to revive its breach of § 8.4 theory, Echo Bay now further undermines its main theory of liability. In the SAC, Echo Bay has abandoned its allegation that no "cessation of the Development of any Active Products in accordance with Section 8.4(a)" took place, and instead alleges that a cessation of Development *did* take place with respect to Fluocinonide. *Compare*

FAC ¶ 52 *with* SAC ¶ 52 (deletion of allegation that “there was not” an express or deemed cessation under § 8.4(a)). Echo Bay’s new allegations concede that § 8.4(a) applies to Torrent’s alleged cessation of the development of Fluocinonide, and limits Echo Bay’s theories of breach and damages to the rights and obligations set forth under § 8.4(a) governing a “deemed cessation of Development.” *Id.* The clear terms of § 8.4(a) on which Echo Bay relies for its new allegations support Torrent’s consistent position that there exists no independent obligation for Torrent to diligently pursue development of the Active Products under the CSA.

Echo Bay cannot assert a claim for breach of contract arising out of alleged conduct—specifically, Torrent’s alleged cessation of development of the Active Products—that was expressly contemplated by the parties and permitted under the contract. *See Peckham Road Co. v. State*, 32 A.D.2d 139, 411 (N.Y. App. Div. 1969) (delays to performance are not actionable if they were within contemplation of the parties at the time the contract was entered); *Andron Constr. Corp. v. Dormitory Auth. Of the State of New York*, 2016 N.Y. Misc. LEXIS 1613, \*30 (N.Y. Sup. Ct. Apr. 22, 2016) (delays expressly contemplated in the contract were not actionable). Accordingly, all of the claims Echo Bay asserts based on its “prudent and reasonable” development theory—including all claims arising out of the alleged failure to develop any of the Active Products other than Fluocinonide—should be dismissed with prejudice.

### **CONCLUSION**

For the foregoing reasons, the Court should dismiss the SAC—and each of Echo Bay’s distinct and inconsistent theories of liability therein—with prejudice.

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August 31, 2021

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